

**Class Determination Request Guideline**

ACVM guideline (June 2022)

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# Introduction

Please use this guideline to help you complete the [request form](https://www.mpi.govt.nz/dmsdocument/2855-acvm-15-class-determination-request-form) for class determination. If you have any questions, contact us by email: approvals@mpi.govt.nz

# Purpose of class determination

The ACVM team undertake class determinations to provide an opinion on the status of a trade name product under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997. All products that fit the definition of an agricultural compound under this Act require registration unless they are described by one of the exemption entries in the [ACVM (Exemptions and Prohibited](http://www.legislation.govt.nz/regulation/public/2011/0327/latest/DLM3982848.html?search=ts_regulation_Agricultural%2B%2BCompounds_resel&amp;p=1&amp;sr=1) [Substances) Regulations 2011.](http://www.legislation.govt.nz/regulation/public/2011/0327/latest/DLM3982848.html?search=ts_regulation_Agricultural%2B%2BCompounds_resel&amp;p=1&amp;sr=1)

The entries for exemption are listed in Schedule 2 of the ACVM Regulations 2011. Read our guideline [Products regulated under the ACVM Act,](https://www.mpi.govt.nz/dmsdocument/2979-products-regulated-under-the-acvm-act) which explains exemption from the registration process in detail and lists prohibited substances and plants.

If your product requires registration, relevant information and forms are available on our website.

**Importing agricultural compounds into New Zealand**

To enable Biosecurity New Zealand to release your product under the ACVM Act at the border you must provide your class determination (CD) advice letter (or a copy). This applies only if your product does not require registration i.e. it is either exempt from registration or does not fit the definition of an agricultural compound under the ACVM Act 1997. To avoid delays with clearance and ACVM inspection costs, it is recommended you seek a class determination at least 15 working days prior to importing a product. Include a copy of your CD advice letter with the declaration information attached to the product to avoid delays at border.

**Class Determination Outcome**

On completion of the class determination, you will receive a class determination advice letter informing you of the status of your product under the Act. The letter will include details of the exemption entry(ies) that may describe your product and advice regarding compliance with the entry(ies) description and conditions.

You have the right to contest the advice. Send these queries electronically to approvals@mpi.govt.nz. (Note: This will be charged on a cost time basis. See Section 3).

 

The advice letter is valid for three years. Any change\* made to the product or any of the other information provided with the application may alter the status of the product. If changes are made, the status of the product can be confirmed by submitting a new application.

\* Change includes any changes to the ingredients, use patterns, claims, statements relating to the way in which the ingredients or product act, or label-referenced website content that differs from the label information on any marketing material or information provided with the product or New Zealand websites controlled by the applicant.

**Note**: If the product is determined to be an agricultural compound that is exempt from the requirement for registration, all aspects of its importation, manufacture, sale or use, are still subject to the requirements stipulated in the Regulations. It is important that the Regulations be read and understood, in addition to the ACVM guideline “[Obligations under the ACVM Regulations](https://www.mpi.govt.nz/dmsdocument/19037-Obligations-under-the-ACVM-regulations)” and the ACVM Notice “[Agricultural Compounds Exempt from Registration](https://www.mpi.govt.nz/dmsdocument/21653-Agricultural-Compounds-Exempt-from-Registration-Requirements-for-conditions-of-exemption)”

## Other requirements

Imported products made from ingredients of biological (plant, animal, or micro-organism) origin must also meet requirements under the Biosecurity Act 1993. See <http://www.mpi.govt.nz/biosecuritynz/> or contact animal.imports@mpi.govt.nz or plantimports@mpi.govt.nz

Imported products containing a live organism and/or a hazardous substance must also meet requirements under the Hazardous Substances and New Organisms (HSNO) Act 1996. See [www.epa.govt.nz](http://www.epa.govt.nz/)

# Timeframe and fees

ACVM aim to complete each class determination within 15 working days. Applications will not be processed until all information requested on the form is received. If further communication or clarification is required, then additional time and/or charges apply.

The initial determination attracts a fee of $155.25 (inc. GST). If multiple product determinations are made under the one application, the first is charged as above with subsequent determinations charged on cost versus time basis at $155.25 (inc. GST)/hr. An initial payment of $155.25 must accompany the application. The remainder will be invoiced if applicable.For multiple products, group together by use, 20 products per application.

If you wish to contest the advice provided any additional time taken in deliberation and responding to the query will be charged at the current hourly rate.

# Request form

## Name and Contact Details

Explained on form.

## 4A Trade Name Product Details: New Application

Enter the legal trade name of the product.

State the active ingredient(s) (that is, the chemical or biological component in the product that is principally responsible for the effect(s) being claimed; distinct from other formulation components such as surfactants, carriers or diluents).

If the label refers to additional documents which describe the product such as safety data sheets (SDS) or data/product specification sheets, please provide these with the initial application.

Enter the use claim for the product. State what crop/ animal species the product is intended for and what the product will be used for (for example, supplement for horses to provide a source of nutrients that may be deficient in the diet). **Information on intended use is essential in making a class determination.**

If multiple applications are made together, please group the products by USE PATTERN.

If applying for more than ten products, please provide product information in an Excel spreadsheet with products grouped by USE PATTERN.

For agricultural chemicals tick the applicable box to identify whether the product is intended only for use in the home garden on non-food/ non-animal feed crops.

## 4B Trade Name Product Details: Renewal Application

Enter the legal trade name of the product and either:

* + - tick the NO box to confirm that nothing has changed (see \*Change in 3 above) since the previous class determination, or
		- tick the YES box and provide details of any information that has changed (see \*Change in 3 above). Highlight changes in the copy of the label provided.

If this information has been previously provided to MPI, confirm that there have been no changes. If not previously provided, include it with the application. A change in the product may require MPI to reassess the existing class determination advice.

As listed in Section 8 of the form, **provide a copy of the previous Class Determination advice letter And Label whether or not there have been any changes.**

##  Websites and Marketing Material (Advertising)

MPI routinely checks advertising as part of the CD process. Frequently, websites and other material referenced on a product label make claims other than those on the product label. Certain claims or other statements may alter the status of the product under the Act and invalidate class determination advice based solely on label content. (For example, if a therapeutic claim such as “treats arthritis” is made on referenced material for a dietary supplement, the product is a veterinary medicine and is not exempt from registration.)

If the intention is to provide information to the New Zealand market that is different from what is on the product label via written, verbal or electronic media, this information should be provided with the CD request form. If such information is not provided and is later found to be inconsistent with the class determination advice given, your product may be non-compliant with legal requirements.

##  For Oral Nutritional Compounds Only

Complete feeds (not supplements such as vitamin tablets) imported from Australia are subject to the Trans -Tasman Mutual Recognition Agreement (TTMRA). It is accepted that due care has been taken to ensure these products are fit for purpose and no further assessment is required in New Zealand. However, we must have the label to ensure there are no therapeutic claims. Products making therapeutic claims are not subject to the TTMRA.

##  Requirements

Explained on application form.

##  Applicant Statement

Explained on application form. Please note that signing the applicant statement is an acknowledgement that you are aware of the continuing obligation to ensure full compliance with all requirements for the exemption status to apply to an ACVM product.

## 10 MPI Service Charge

Payment may be made by direct credit, credit card or cheque. Please follow the instructions on the application form. Payment should accompany the application. No class determination will be carried out until payment is received.